

Changes to Electronic Submission guidance.

The following changes have been made to the Electronic Submission and Review guidance posted on the web site. Over time, circumstances will arise that require changes to the posted guidance. Please consult this list for changes and updates to previously posted documents.

October 22, 2002	
Change	Guidance Document
Added the residue chemistry template for Food Handling Establishment studies.	Food Handling Establishments–OPPTS 860.1460
Made assorted changes to all of the residue chemistry templates as follows:	
Added “Reference” column to Table 2–Physicochemical Properties.	All residue chemistry templates.
Added references to Canada and US and rotated the table (columns became rows, rows became columns) in Table 5–Trial Numbers and Geographic Locations. Added column “n” in Table 9–Summary of Residue Data from Crop Field Trials with [chemical].	Crop Field Trial–OPPTS 860.1500
Deleted entire Table 3–Trial Numbers and Geographic Locations. Added column “Harvest DAP” in Table 6–[Chemical] Residues in Rotational Crops.	Field Accumulation in Rotational Crops–OPPTS 860.1900
Deleted column “Gender” in Table 3–Description of Livestock Used in the Feeding Study. Deleted entire Table 4–Treatment Groups and Feeding Levels. Added column “n” in Table 11–Summary of Residue Data from [ruminant/poultry] Feeding Study with [chemical].	Livestock Feeding Study–OPPTS 860.1480
Deleted column “RAC or Extract” in Table 8–Summary of Storage Conditions. Added column “Collection timing” in Table 9–Total Radioactive Residues (TTRs) in Milk/Eggs, Tissues, and Excreta. Changed instructional text in Tables 10–Distribution of the Parent and the Metabolites in Livestock Matrices when Dosed with ¹⁴ C-Labeled test Compound X. and Table 11–Summary of Characterization and Identification of Radioactive Residues in Livestock Matrices Following Application of Radiolabeled [chemical] at [rate].	Nature of the Residues in Livestock–OPPTS 860.1300

Change	Guidance Document
Added column “Storage interval (days)” in Table 3–Summary of Concurrent Recoveries of [chemical] from [matrix].	Storage Stability–OPPTS 860.1380
Added references to Canada and US and rotated the table (columns became rows, rows became columns) in Table 10– Trial Numbers and Geographic Locations. Added column “n” in Table 18– Summary of Residue Data from [type of study (irrigated crops, fish, water)] with [chemical].	Water, Fish, Irrigated Crops–OPPTS 860.1400
Added column “Timing and application no.” and deleted row “Total recovery” from Table 8–identification, Characterization, and Distribution of Residues. Changed instructional text for Table 10–Summary of Characterization and Identification of Radioactive Residues in Plant Matrices Following Application of Radiolabeled [chemical] at [rate].	Nature of the Residues in Plants–OPPTS 860.1300

October 1, 2002	
Change	Guidance Document
Clearly indicate on the transmittal document which specific studies are to be submitted electronically.	Preparation and In-Processing of Studies Submitted in PDF. Page 2.
When referencing guidelines [in the directory structure of the CD], use whichever guideline set (old vs. harmonized) is appropriate for the study.	Preparation and In-Processing of Studies Submitted in PDF. Page 3.
The full path name of all files on the CD must be less than 200 characters in length including all folders, subfolders, and file name. The actual PDF file name may be of any length as long as the 200 character limit for the full path on the CD is not exceeded.	Specifications for Creating PDF Versions of Study Reports. Page 5.

Use the MRID as the first 8 characters of the supplemental file name to which it relates This guidance is similar to that specified for the naming convention of the actual study report PDF file.	Specifications for Creating PDF Versions of Study Reports. Page 5.
Addition of the Residue Chemistry templates to the web site.	Electronic Submission and Review—Guidance Documents.
Addition of this changes to e-sub document to the web site.	Electronic Data Submission and Review Efforts.